

AMENDMENTS TO THE CLAIMS

Claims 1-2 (Cancelled)

Claim 3 (Currently Amended) A pharmaceutical composition which can be administered orally, consisting essentially of efletirizine as active principle, with at least one fraction which allows immediate release of the efletirizine and at least one fraction which allows prolonged release of the efletirizine, the respective amounts of active principle in the two fractions being the values included on or between the two straight lines defined by the following equations:

$$Y = -0.6786X + 56.675$$

$$Y = -0.6636X + 7.975$$

in which,

Y represents the amount of efletirizine in milligrams (mg) in the immediate-release fraction, and

X represents the amount of efletirizine in milligrams (mg) in the prolonged-release fraction, and

the total amount $X + Y$ being between 10 and 70 mg;
wherein

the two fractions are provided in the form of a two-layer tablet,
wherein

the weight ratio of the amount of active principle in the immediate-release fraction to the amount of active principle in the prolonged-release fraction is between 3 and 0.025,

wherein

the prolonged-release fraction contains an excipient of matricial type,
wherein

the immediate-release fraction contains an excipient selected from the group consisting of diluents, binders, disintegrating agents, lubricants and flow enhancers, taste-masking agents, flavorings and colorants
and wherein

the composition is a single daily dose having bioequivalence to two
administrations of 5-25 mg of efletirizine in an immediate release form given 12 hours
apart, while obtaining the desired therapeutic effect.

Claim 4-5 (Cancelled)

Claim 6 (Previously Presented) The composition as claimed in claim 3, wherein the fraction which allows prolonged release of the efletirizine contains less than 5% by weight of basifying agent, weight relative to the total weight of the fraction.

Claim 7 (Cancelled)

Claim 8 (Previously Presented) The composition as claimed in claim 3, wherein the fraction which allows prolonged release of the efletirizine contains 25 mg of efletirizine and the fraction which allows immediate release of the efletirizine contains 10 mg of efletirizine.

Claim 9 (Previously Presented) The composition as claimed in claim 3, wherein the weight ratio of the amount of efletirizine in the immediate-release fraction to the amount of efletirizine in the prolonged-release fraction is between 1.6 and 0.05.

Claim 10 (Currently Amended) The composition as claimed in claim 3, wherein the prolonged-release fraction contains as excipients dibasic calcium phosphate hydrate, hydroxypropylmethylcellulose, microcrystalline cellulose, colloidal silica and magnesium stearate
and wherein

the immediate release fraction contains as excipients lactose monohydrate, monocrystalline-microcrystalline cellulose, colloidal silica, and magnesium stearate.

Claim 11 (New) The composition as claimed in claim 8, wherein the composition is a single daily dose having bioequivalence to two administrations of 15 mg of efletirizine in an immediate release form given 12 hours apart.

Claim 12 (New) The composition as claimed in claim 11, wherein the prolonged release fraction contains 28.4 mg of hydroxypropylmethylcellulose.

Claim 13 (New) The composition as claimed in claim 12, wherein the prolonged release fraction contains 30 mg dibasic calcium phosphate, 1.7 mg polyvinylpyrrolidone, 0.6 mg colloidal silica and 0.8 mg magnesium stearate.

Claim 14 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is selected from one or more of the group consisting of inert matrices, hydrophilic matrices and lipophilic matrices.

Claim 15 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is an inert matrix at a concentration ranging from 20 to 95% consisting essentially of one or more thermoplastic polymers.

Claim 16 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is an inert matrix at a concentration ranging from 20 to 95% selected from one or more of the group consisting of polyvinyl chloride, polyethylene, copolymers of vinyl acetate and vinyl chloride, poly(methyl methacrylates), polyamides, silicones, ethylcellulose, and polystyrene.

Claim 17 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a hydrophilic matrix at a concentration of 20 to 70%.

Claim 18 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a hydrophilic matrix comprising one or more gelling excipients at a concentration of 20 to 70% selected from the group consisting of cellulose derivatives, non-cellulose polysaccharides and acrylic acid polymers.

Claim 19 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a hydrophilic matrix comprising one or more gelling excipients at a concentration of 20 to 70% selected from the group consisting of hydroxypropylmethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, methylcellulose, galactomannans, guar gum, carob gum, gum arabic, sterculia gum, agar agar, alginates, carbopol 934P and carbopol 974P.

Claim 20 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50%.

Claim 21 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50% selected from one or more of the group consisting of glycerides, fatty acids, fatty alcohols, fatty acid esters and waxes.

Claim 22 (New) The composition as claimed in claim 1, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50% selected from one or more of the group consisting of monoglycerides, diglycerides, triglycerides, stearin, palmitin, laurin, myristin, hydrogenated castor or cottonseed oil, precirol, stearic acid, palmitic acid, lauric acid; stearyl alcohol, cetyl alcohol, cetostearyl alcohol, monostearates of propyleneglycol and of sucrose, sucrose distearate, white wax, and sperm whale wax.